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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,843	05/18/2006	Lorenza Mariscal-Gonzalez	UHT1.001APC	2198

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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
01/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/540,843	MARISCAL-GONZALEZ ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-31 and 38-43* is/are pending in the application.

4a) Of the above claim(s) *10-15, 17-21 and 24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,16,22,23,31 and 38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *June 27, 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention I and the required species in the replies filed on December 12, 2007, April 28, 2008 and October 7, 2008 is acknowledged.

Claims 10-15, 17-21 and 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 12, 2007, April 28, 2008 and October 7, 2008.

Claims 8, 9, 16, 22, 23, 31 and 38-43 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 27, 2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Objections

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification is objected to because the drawing description for figures 7A-C do not contain specific SEQ ID NO:s.

Applicants must comply with sequence rules in order to be considered a complete response to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 9, 16, 22 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Redmond and Campos (US Pat. 5,503,833).

The claimed invention is drawn to a pharmaceutical composition (with an acceptable vehicle) for the delivery of a hormone comprising: (A) a hormone; and (B) an effective amount of rotavirus protein VP4, or its derived polypeptide VP8: its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them as well as their mixtures. In addition, the pharmaceutical composition is an oral dosage composition for intestinal delivery of

the therapeutic agent, and administering is by oral administration. For purposes of examination, "functional variants" as it relates to VP4 rotavirus proteins includes other rotavirus structural, envelope proteins (i.e., VP6, VP7, etc.).

Redmond and Campos teach the development of a drug delivery virus-like particle (VLP) based on rotavirus VP6. Redmond and Campos teach that such virus-like particles can be employed to target compounds of interest by encapsulating such compounds. Moreover, Redmond and Campos teach that hormones such as, insulin-like growth factor, glucagon, prolactin and neurotensin can be encapsulated by VLPs. Redmond and Campos also teach that VP6 encapsulated substances can also be formulated for the intended route of administration (i.e., oral, nasal, etc.) Lastly, since rotaviruses target intestinal cells, a VLP based on VP6 would inherently target intestinal cells. Therefore, Redmond and Campos anticipated the claimed invention. *See columns 4, 6 and 7.*

Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession # AAK52093 (July, 2001).

The claimed invention is drawn to an isolated peptide with SEQ ID NO: 3. For purposes of examination, "with SEQ ID NO: 3" is interpreted to include any peptide that contains the SEQ ID NO: 3 within its amino acid sequence.

The Rhesus rotavirus VP4 peptide accessioned under # AAK52093 contains SEQ ID NO: 3 between residues 141 and 182. Therefore, AAK52093 anticipate the claimed invention.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession # AAK52093 (July, 2001).

The claimed invention is drawn to an isolated peptide with SEQ ID NO: 4 (amino acids VVKT). For purposes of examination, "with SEQ ID NO: 4" is interpreted to include any peptide that contains the SEQ ID NO: 4 within its amino acid sequence.

The Rhesus rotavirus VP4 peptide accessioned under # AAK52093 contains SEQ ID NO: 4 between residues 143 and 146. Therefore, AAK52093 anticipate the claimed invention.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Hendrick et al. (PNAS, 1989).

The claimed invention is drawn to an isolated peptide with SEQ ID NO: 5 (amino acids SYSQYGPL). For purposes of examination, "with SEQ ID NO: 5" is interpreted to include any peptide that contains the SEQ ID NO: 5 within its amino acid sequence.

Hendrick et al. teach various mitochondrial leader peptides, one of which contains SEQ ID NO: 4 (see Reference #36 in figure 1). Therefore, Hendrick et al. anticipate the claimed invention.

Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession # AAK52093 (July, 2001).

The claimed invention is drawn to an isolated peptide with SEQ ID NO: 6 (amino acids IYTY). For purposes of examination, "with SEQ ID NO: 6" is interpreted to include any peptide that contains the SEQ ID NO: 6 within its amino acid sequence.

The Rhesus rotavirus VP4 peptide accessioned under # AAK52093 contains SEQ ID NO: 6 between residues 174 and 177. Therefore, AAK52093 anticipate the claimed invention.

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Ginger et al. (Development, 1998).

The claimed invention is drawn to an isolated peptide with SEQ ID NO: 7 (amino acids NVTT). For purposes of examination, "with SEQ ID NO: 7" is interpreted to include any peptide that contains the SEQ ID NO: 7 within its amino acid sequence.

Ginger et al. teach the cell surface protein *dtfA* from *Dictyostelium* that contains SEQ ID NO: 7 (see figure 3A). Therefore, Ginger et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9, 16, 22, 23, 31 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Redmond and Campos (US Pat. 5,503,833) and Cao and Lam (Drugs of Today, 2002).

The claimed invention also includes the use of insulin as the hormone.

The teachings of Redmond and Campos are discussed above, however, they do not specifically state that insulin is used.

Cao and Lam teach that technology focusing on the oral administration of insulin is being developed. *See abstract.*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Redmond and Campos in order to encapsulate insulin with a VP4 or a functional derivative, thereby formulating an oral composition that will target intestinal cells. One would have been motivated to do so, given the suggestion by Redmond and Campos that the composition be used to encapsulate hormones such as insulin-like growth factor. There would have been a reasonable expectation of success, given the knowledge that oral administration of insulin is of great interest in the treatment of diabetes, as taught by Cao and Lam. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648